DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2005

Kowa Company, Ltd.
% Richard N. Phillips, Ph.D.
1801 Rockville Pike
Suite 300
Rockville, MD 20852

Re: K043213
Trade/Device Name: Kowa VX-10
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 27, 2005
Received: September 28, 2005

Dear Dr. Phillips:

This letter corrects our substantially equivalent letter of October 6, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K043213

Device Name: Kowa VX-10 Fundus Camera

Indications For Use:

Kowa VX-10 is intended for taking pictures of fundus images with mydriatic or without mydriatic.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Buttemer, DOED

OCT 6 - 2005

K043213

9. Certification
9.1 Summary for public disclosure

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-3-3279-7329 Fax: +81-3-3279-7541
Contact:	Satohiko Takanashi
Date summary prepared:	Nov. 18, 2004

Device identification:

Device trade name:	KOWA VX-10
Classification name:	CAMERA, OPTHALMIC, AC-POWERED
Product code:	HKI

Intended use:

KOWA VX-10 is intended for taking pictures of fundus images with mydriatic or without mydriatic.

Comparison:

As a substantial equivalent device, CANON Non-Mydriatic Retinal Camera, Model Cr6-45nm (referred to as CANON Cr6-45nm hereafter) and KOWA PROFESSIONAL FUNDUS CAMERA MODEL FX-500 (referred to as FX-500 hereafter) were selected.

KOWA VX-10 is a fundus image shooting device which delivers both functions of mydriatic and non-mydriatic, and is capable of shooting with 35mm film, Polaroid film or video camera by replacing the shooting unit in a similar to the predicate devices. The non-mydriatic function uses infrared light as does CANON Cr6-45nm, and alignment and focusing are made from the built-in monitor. A Xenon flash lamp is used for shooting. When mydriatic shooting function is used, visible light is used for observation, and alignment and focusing are made manually by looking into the finder as in FX-500. A Xenon flash lamp is used for shooting. Furthermore, like FX-500, it is capable of fluorescein angiographic fundus shooting.

KOWA VX-10 has two image shooting magnifications, narrow node and normal mode. The normal mode is same image shooting magnifications to the predicate devices. The narrow mode of image shooting magnifications is narrower than the predicate devices, and more detailed shooting of the affected area is possible.

KOWA VX-10 delivers safety equivalent to that of the predicate devices.
A comparison among the functions of KOWA VX-10 and the predicate devices is provided in the comparison table.

Conclusion:

KOWA VX-10 is equipped with the fundamental technology features equivalent to the

Predicate Device	Manufacturer	510(k)No.	Date Cleared
Non-Mydriatic Retinal Camera, Model Cr6-45nm	CANON U.S.A., Inc.	K980246	05/06/1998
KOWA PROFESSIONAL FUNDUS CAMERA MODEL FX-500	Kowa Optimed, Inc.	K954780	12/01/1995

predicate devices, and also delivers the equivalent level of safety.
Thus it is concluded that there is no difference in the basic functions and safety between KOWA VX-10 and the predicate devices.

Predicate device comparison table

	KOWA VX-10	Non-Mydriatic Retinal Camera, Model Cr6-45nm	FX-500
Indications For Use	Taking pictures of fundus images with or without mydriatic.	Taking pictures of retina of human eye without mydriatic.	Taking pictures of eye with mydriatic.
Picture magnifications	Mydriatic: 50° /25° Non-mydriatic: 45° /22°	Non-mydriatic: 45° /30°	Mydriatic: 50° /35°
Working distance	39 mm	45 mm	38 mm
CCD camera for observation	Same as the Cr6-45nm	Monochrome CCD	None
Record media	Same as the both	35mm film / Polaroid film	35mm film / Polaroid film
Video camera connect ability	Same as the Cr6-45nm	Yes	No
Observation system	Mydriatic: Same as the Fx-500 Non-mydriatic: LCD	CRT	Optical finder
Dioptric compensation	-32D ~ +35D	-33D ~ +35D	-25D ~ +45D
Focusing	Same as the Cr6-45nm	By aligning the split lines	By focusing two oscillating points
Filter for FA	Present	Not	Preset
Observation Light Source	Same as the FX-500	Halogen lamp 75W	Halogen lamp 50W
Photographing Light Source	Same as the both	Xenon flash lamp 300WS	Xenon flash lamp 300WS